

A priority claim to earlier copending application has been added, and a new first page attached hereto as believed to be required by the new rules. The abstract is amended as required (attached).

Claims 4, 5, 7, 14 and 15 are objected to under 37 CFR 1.75c as allegedly being of improper dependent form; Applicant respectfully traverses these objections. Claim 4 is replaced with claim 18 to more expeditiously remove the parenthetical markings objected to in claim 4. Claims 1 and 12 are replaced by claims 17 and 19 to more clearly articulate that the claims are drawn to compositions of matter, the matter selected for specified efficacy. The remaining objected to claims now depend from the new replacement claims, and as such are not subject to the same conditions as may have prevailed with respect to the original claims. All these claims, as replaced, or newly dependent, are now believed to overcome the objection, and reconsideration is requested.

Claims 1, 4-7, 12, 14 and 15 stand rejected under 35 USC §102 as allegedly anticipated by Hastings, US Patent 6,224,871 issued May 1, 2001. Applicant respectfully traverses these grounds of rejection. Hastings was filed March 11, 1998, ahead of the August 30, 1998 priority date of this case by only a few months, but not ahead of the earliest priority date to which Applicant can claim conception and reduction to practice of the therapeutic use of plant matter derived from *Uncaria tomentosa*. Applicant's Rule 131 declaration attached hereto makes it clear that the inventors had conceived of the therapeutic use of *Uncaria tomentosa* ahead of Hastings' filing date, and then diligently reduced their invention to practice by first filing a provisional in May of 1997 and then Ser. No. 09/079,829 on May 15, 1998 broadly disclosing and claiming compositions and methods for using plant matter derived from *Uncaria tomentosa* to treat Alzheimer's disease and other amyloidoses. The only commonality between Hastings disclosure and the rejected claims as amended (or replaced) is the therapeutic use of *Uncaria tomentosa*. But

Applicants conceived of this novel therapeutic use well in advance of Hastings' filing date (Declaration of Snow). Hastings should therefore be withdrawn as a reference under section 102(e) as inappropriate in view of the Rule 131 Declaration of Snow. Claims 1 and 12 and their respective dependents are all therefore not anticipated by the art of record, but are in fact allowable, and reconsideration is requested.

Applicant believes that he responded fully to all of the concerns expressed by the Examiner in the Office Action, and respectfully requests that new Claims be entered and examined, and that early favorable action be taken on all claims pending in the application. Applicant respectfully requests reexamination of all rejected claims and early favorable action on them as well. If the Examiner has any further concerns, Applicant requests a call to Applicant's attorney Patrick Dwyer at (206) 343-7074.

Respectfully submitted,



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## Amended Claims

### Version with Markings to Show Changes Made

2. (Amended) The pharmacological agent of claim ~~1~~17 wherein the therapeutically effective amount of *Uncaria tomentosa* comprises a dosage in the range of from about 10 to 1,000 mg/kg of body weight of the patient.
5. (Amended) The pharmacological agent of claim ~~4~~18 wherein said amyloid disease for treatment is Alzheimer's Disease.
6. (Amended) The pharmaceutical agent of claim ~~1~~17 further comprising a pharmaceutically acceptable carrier, diluent or excipient.
7. (Amended) The pharmaceutical agent of claim ~~1~~17 wherein the therapeutically effective amount of plant matter has an amyloid inhibitory activity or efficacy greater than 50%.
8. (Amended) A method of treating an amyloid disease in a patient, comprising the step of administering to the patient a therapeutically effective amount of plant matter from a plant of the genus *Uncaria*, species *tomentosa*, in combination with a therapeutically effective amount of one or more ~~or the substances~~ selected from the group of substances consisting of Ginkgo Biloba, Ginseng, Gotu Kola, Echinacea, Vitamin E, Selenium, Niacin or nicotinate, Folic acid, Vitamin B12 or cobalamin, and Choline.
13. (Amended) The pharmacological agent of claim ~~12~~19 wherein the therapeutically effective amount of *Uncaria tomentosa* comprises a dosage in the range of from about 10 to 100 mg/kg of body weight of the patient.
14. (Amended) The pharmacological agent of claim ~~12~~19 wherein said amyloid disease for treatment is Diabetes.
15. (Amended) The pharmaceutical agent of claim ~~12~~19 wherein the therapeutically effective amount of plant matter has an amyloid inhibitory activity or efficacy greater than 50%.

16. (Amended) A method of treating an amyloid disease in a patient, comprising the step of administering to the patient a therapeutically effective amount of plant matter from a plant of the genus *Uncaria*, species *tomentosa*, in combination with a therapeutically effective amount of one or more ~~or the substances~~ selected from the group of ~~substances~~ consisting of Bilberry, Dong Quai, Aloe Vera, Chromium Polynicotinate, Selenium, Vitamin B12 or cobalamin, Folic acid, Biotin, and Thiamine HCl, or vitamin B1.

#6  
9-786034

5 Title: BLENDED COMPOSITIONS FOR TREATMENT  
OF ALZHEIMER'S DISEASE AND OTHER AMYLOIDOSES

This application is the US national entry of PCT/US99/19721 filed August 30,  
1999 which claims priority to US Provisional Application No. 60/098,473 filed August  
10 31, 1998 and which is a continuation in part of US Patent Application No. 09/079,829  
filed May 15, 1998.

TECHNICAL FIELD

The invention relates to blended compositions for treating Alzheimer's Disease  
and other amyloidoses; more particularly, it relates to blended compositions for  
15 therapeutic intervention in Alzheimer's disease and other amyloidoses.

BACKGROUND OF THE INVENTION

Brain Amyloid Prevention and Memory / Recall Optimization

It is known that amyloid accumulates in the brains of people as they age. This  
amyloid is most commonly and most deleteriously in the form of what are known as  
20 amyloid plaques. In addition there are amyloid deposits in cerebral blood vessels. These  
accumulations form a brain amyloid burden that increases with age, so that age is a risk  
factor for Alzheimer's disease and other amyloidoses.

One of the most notable effects of increasing brain amyloid burden, and especially  
in Alzheimer's Disease, is the gradual deterioration of short term memory; that is, the  
25 ability to recall immediately those memories only recently stored.

Alzheimer's disease in general is characterized by the accumulation of a 39-43  
amino acid peptide termed the beta-amyloid protein or A $\beta$ , in a fibrillar form, existing  
as extracellular amyloid plaques and as amyloid within the walls of cerebral blood  
vessels. Fibrillar A $\beta$  amyloid deposition in Alzheimer's disease is believed to be  
30 detrimental to the patient and eventually leads to toxicity and neuronal cell death,

## ABSTRACT OF THE INVENTION

A pharmacological agent that is a therapeutically effective amount of plant matter from a plant of the genus *Uncaria*, species *tomentosa*, in combination with a therapeutically effective amount of one or more of Ginkgo Biloba, Ginseng, Gotu Kola, Vitamin E, Selenium, Niacin or nicotinate, Folic acid, Vitamin B12, or Choline. The plant matter and substance and the therapeutic amount of the plant matter and substance are selected for efficacy in treating an amyloid disease such as Alzheimer's disease in a patient. A method of treating an amyloid disease in a patient that includes administering to the patient a therapeutically effective amount of the above composition is also disclosed. A pharmacological agent that is a therapeutically effective amount of plant matter from a plant of the genus *Uncaria*, species *tomentosa*, in combination with a therapeutically effective amount of one or more of Dong Quai, Chromium Polynicotinate, Selenium, Vitamin B12 or cobalamin, Folic acid, Biotin, and Thiamine HCl, or vitamin B1. The plant matter and substance and the therapeutic amount of the plant matter and substance selected for efficacy in treating an amyloid disease in a patient. A method of treating an amyloid disease in a patient that includes administering to the patient a therapeutically effective amount of the above composition is also disclosed.